

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

THIS PAGE BLANK (USPTO)



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁴ : A61M 5/32	A1	(11) International Publication Number: WO 87/ 06474 (43) International Publication Date: 5 November 1987 (05.11.87)
---	-----------	---

(21) International Application Number: PCT/US87/00967

(22) International Filing Date: 29 April 1987 (29.04.87)

(31) Priority Application Number: 858,134

(32) Priority Date: 30 April 1986 (30.04.86)

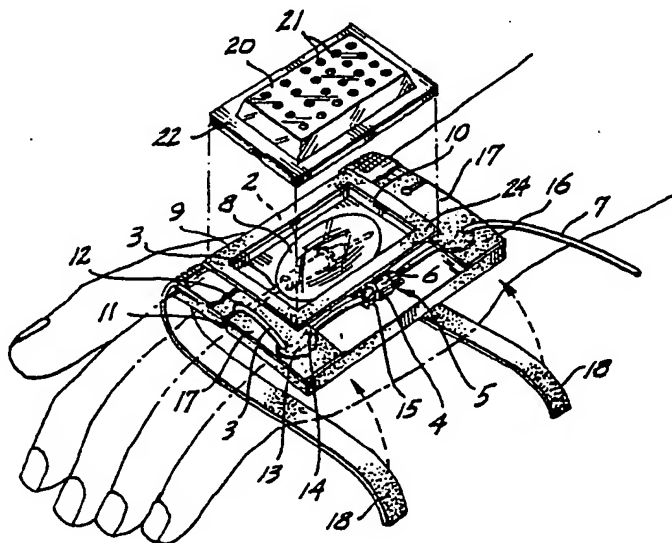
(33) Priority Country: US

(71)(72) Applicant and Inventor: SAFADAGO, Gary, Joseph
[US/US]; P.O. Box 15454, Seattle, WA 98115 (US).(74) Agent: BROWN, Ward; Beach & Brown, 3107 Eastlake
Avenue East, Seattle, WA 98102 (US).

(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).

Published*With international search report.*

(54) Title: IV TUBE ANCHOR AND SHIELD



(57) Abstract

A continuous frame (9) of resilient foam material is strapped to a patient with a central aperture (10) of the frame (9) surrounding the puncture area of an intravenous (IV) needle (1) inserted into the patient. A separate dome (20) with ventilation apertures (21) is attachable over the central aperture (10) of the frame (9) to shield the needle (1, 2). The IV tube (3, 7) is anchored to the frame (9) at a plurality of different locations such that tension applied to the tube (3, 7) is not transmitted to the needle (1, 2) to dislodge it.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	ML	Mali
AU	Australia	GA	Gabon	MR	Mauritania
BB	Barbados	GB	United Kingdom	MW	Malawi
BE	Belgium	HU	Hungary	NL	Netherlands
BG	Bulgaria	IT	Italy	NO	Norway
BJ	Benin	JP	Japan	RO	Romania
BR	Brazil	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	LI	Liechtenstein	SN	Senegal
CH	Switzerland	LK	Sri Lanka	SU	Soviet Union
CM	Cameroon	LU	Luxembourg	TD	Chad
DE	Germany, Federal Republic of	MC	Monaco	TG	Togo
DK	Denmark	MG	Madagascar	US	United States of America
FI	Finland				

-1-

Description

IV Tube Anchor and Shield

Technical Field

This invention relates to a device that can be strapped to the body over the location of insertion of an intravenous (IV) needle to shield the puncture
5 area against contact and for anchoring the IV tube so that the needle will not be pulled out inadvertently.

Background Art

It is known to apply a self-adhesive sheet, film or membrane over the area of insertion of an IV
10 needle into the body, primarily for the purpose of keeping the area clean. The covering sheet does not substantially protect or anchor the needle or IV tube.

The rigid connector between an IV needle and its tube sometimes is covered by a small plastic pill
15 cup which is taped to the body, but the cup does not offer substantial protection against dislodging the needle by tension exerted on the tube.

The problem of protecting the area of the body into which an IV needle has been inserted and
20 anchoring the IV tube in such manner that dislodging it inadvertently is unlikely is of particular importance for children with an illness requiring frequent or prolonged hospitalization. Under current techniques, a child quickly develops a fear of the needle and goes to
25 extremes in trying to protect it, yet may inadvertently dislodge the needle, sometimes while asleep. Consequently, the activity of the child can be affected adversely and, of course, the health of the child may be jeopardized if dislodgment of the needle is not
30 detected for a substantial period. In addition, it can be extremely important that an IV needle remain

-2-

inserted as intended if there are few or no remaining veins accessible without surgery.

Disclosure of the Invention

5 The IV tube anchor and shield of the present invention preferably utilizes a continuous frame of resilient foam material with a central aperture of a size sufficient to surround the puncture area of the IV needle. A separate dome or shield with ventilation apertures is attachable over the central aperture of the frame. The IV tube is threaded through a slot and under tabs in the frame to a return bent, or, preferably, serpentine path, and is maintained in position by straps which also secure the frame and dome combination to the body. The IV or other needle for introducing therapeutic liquid is shielded and is anchored closely adjacent to the point of insertion such that painful contact of an object with the IV needle is unlikely and tension applied to the IV tube will not be transmitted to the needle so as dislodge the needle. The tube anchor and shield is in simple, compact, inexpensive form, easy to use and reliable for shielding the IV needle and anchoring the IV tube for a longer period even on infants or children.

Brief Description of the Drawings

25 Figure 1 is a diagrammatic top perspective of an IV tube anchor and shield in accordance with the present invention with some parts only partially assembled, illustrating application of the device to the back of the hand of a patient;

30 Figure 2 is an enlarged, fragmentary, top perspective of a corner portion of the IV tube anchor and shield shown in Figure 1;

Figure 3 is a top perspective of the IV tube anchor and shield shown in Figure 1, but with parts

-3-

assembled, illustrating application of the device to the underside of the wrist of a patient;

Figure 4 is a section along line 4--4 of Figure 3;

5 Figure 5 is a top perspective of a slightly a slightly modified form of an IV tube anchor and shield in accordance with the present invention mounted on a larger cuff;

10 Figure 6 is a side elevation showing such modified form and cuff of Figure 5 applied to the foot of a patient; and

15 Figure 7 is a front elevation of the upper body portion of a patient with an IV tube anchor and shield in accordance with Figure 1 applied over the chest.

Best Modes for Carrying Out the Invention

Figure 1 illustrates a representative type of IV needle 1 and its immediately adjacent rigid needle and tube connector holder connector 2 with the usual
20 narrow IV tube 3 that extends to the male component 4 of a joint 5. Such joint includes the female component 6 on the end of the usually larger IV tube 7 which extends to a metering device controlling the flow of therapeutic liquid from a bottle or other reservoir.
25 The needle is inserted into a convenient vein which may be on the back of the hand as shown in Figure 1. The rigid needle holder 2 and immediately adjacent area usually are covered by a thin sheet, film or membrane 8 which has a self-adhesive bottom surface and which is
30 intended to keep the puncture area clean.

In accordance with the present invention, the area of insertion of the needle 1 and its holder 2 is surrounded by an anchor member or frame 9. The frame has a central aperture 10 fitted over the covering
35 sheet 8. The short narrow section of IV tube 3 from the rigid holder and connector 2 to the joint 5 extends under an end of frame 9 and upward through a slot 11.

-4-

The inner portion 12 of the slot can be slightly enlarged to snugly retain the tube in position without crimping or kinking it. Next, the tube section 3 is fitted under a tab 13 in an adjacent corner portion of the frame. As seen in Figure 2, the tab 13 can be bent upward so that the tube can be inserted under it. Preferably, the tab is integral with the remainder of the frame and is formed by a generally U-shaped slit with enlarged circular portions 14 at the opposite ends for snugly receiving the tube without kinking or crimping it.

The joint 5 joining the tube sections 3 and 7 can be fitted in a recess 15 in the frame, at the same side of the frame as the corner tab 13. The other corner portion of the frame at the same side has a tab 16 identical to the tab 13 for receiving the tube section 7.

The opposite ends of the frame have strips of fastening material 17, preferably the hook type material of hook-and-pile fastenings. Straps 18 of the pile, loop or foam type fastening material which is complementary to the hook type fastening material can be looped around the hand and wrist for securing the frame in position. As best seen in Figures 3 and 4, preferably the straps extend directly over the tabs 13 and 16 to hold the tabs down and prevent the tubes 3 and 7 from escaping.

In assembled condition, the IV tube 3, 7 is turned at the frame slot 11, again at tab 13 and again at tab 16. Preferably the tube is return bent at least once and follows a serpentine path. The tube is anchored to the frame at two, preferably at least three, of the turns of such path, making it extremely unlikely that tension applied to the tube 7 will be conveyed to the tube section 3 adjacent to the rigid connector 2 so as to dislodge the needle.

In the preferred embodiment, the central aperture 10 of the frame 9 can be closed by a removable rigid dome or shield 20 having ventilation apertures

-5-

21. The dome can have a flat marginal flange portion
22 with one type of the complementary fastening
material along the underside of the flange to mate with
the other type of fastening material arranged in a
5 circumferential strip 24 along the top margin of the
frame aperture. With the shield in position, the
puncture area is substantially enclosed.

In the preferred embodiment, the frame is
somewhat resilient and flexible closed cell foam
10 material of a thickness of about 1/4 inch (.63 cm) to
about 1/2 inch (1.27 cm).

Figure 3 illustrates the assembled frame,
strap and dome construction as applied to the underside
of a patient's wrist. As seen in Figure 4, if the
15 frame is of a thickness less than the height of the
rigid needle holder portion 2, the dome or shield 20
must have a concave underside allowing room for such
holder and protecting the holder and needle from
inadvertent contact.

20 The slightly modified frame 9' shown in
Figure 5 is identical to the frame shown in Figures 1
through 4 with the exception that strips 30 of one type
of the hook-and-pile fastening material are secured to
the underside of the frame 9' along its longitudinal
25 side edges to adapt the frame for attachment over a
cuff 31. The cuff is contoured to fit around the
bottom of the foot and the back of the ankle portion of
a patient as shown in Figure 6 and can be secured in
position by quick-coupling straps 32. The frame 9' is
30 positioned over the top of the foot, between the
opposite sides of the cuff, where there is a vein which
can be used for intravenous introduction of liquid.
Additional straps 18' extend over the opposite ends of
the frame to retain its tabs 13 and 16 in position
35 after the IV tube sections 3 and 7 have been fitted
under them. Consequently, the frame is maintained
securely in position over the top of the foot to

-6-

protect the IV needle inserted in that location which is common for hospitalized children.

Figure 7 illustrates the assembled combination of frame 9, straps 18 and dome 20 as applied over the chest of a patient. Straps 18 are looped over one of the patient's shoulders and have their opposite end portions secured to a larger chest strap 40 at the front and back of the patient, respectively. Insertion of an IV needle in the chest area may be desired for dialysis, chemotherapy or infant intravenous feeding. As in the previously described embodiments, the puncture area is protected by the dome or shield 20 and the IV tube 3, 7 extends through the frame end slot 11 and under the corner tabs 13 and 16 which are held down by one of the straps 18--such straps preferably having patches or strips of fastening material positioned for mating with complementary patches or strips of fastening materials mounted on the frame 9 to hold the tabs down and secure the frame in position.

-7-

Claims

1. Mechanism for protecting an IV needle inserted in a patient and having an IV tube extending therefrom comprising an anchor member, means for securing said anchor member to the body of the patient adjacent to the puncture area of the IV needle, and means for securing the IV tube to the anchor member.

2. Mechanism for protecting an IV needle inserted in a patient and having an IV tube extending therefrom comprising a continuous frame having a central aperture, means for securing said frame to the patient with said aperture surrounding the puncture area of the IV needle, and means for anchoring the IV tube to said frame.

3. The mechanism defined in claim 2, including a shield closing the frame aperture for covering the puncture area of the IV needle and thereby protect it against contact.

4. The mechanism defined in claim 3, in which the shield is a dome manually separable from the frame.

5. The mechanism defined in claim 3, in which the shield has ventilation apertures.

6. The mechanism defined in claim 2, in which the anchoring means includes means for anchoring the IV tube to the frame at at least two different locations.

7. The mechanism defined in claim 6, in which the anchoring means is constructed and arranged to maintain the IV tube in return bent condition.

-8-

8. The mechanism defined in claim 2, in which the anchoring means includes means for anchoring the IV tube to the frame at at least three spaced locations and constructed and arranged to maintain the IV tube in serpentine condition.

9. The mechanism defined in claim 2, including an ankle cuff and means for securing said ankle cuff to the lower leg of the patient, the securing means including means for securing the frame to the ankle cuff over the foot of the patient.

10. The mechanism defined in claim 2, including a chest strap, the securing means including additional straps looped over a shoulder of the patient, positioning the frame over the chest area of the patient and having opposite end portions secured to said chest strap at the front and back of the patient, respectively.

11. Mechanism for protecting an IV needle inserted in a patient and having an IV tube extending therefrom comprising an anchor member having a tab bendable relative to the remainder of said anchor member for insertion of the IV tube thereunder to retain the IV tube, and means for securing said anchor member to the patient adjacent to the puncture area of the IV needle.

12. The mechanism defined in claim 9, in which the securing means includes a strap for extending over the tab.

Fig. 1.

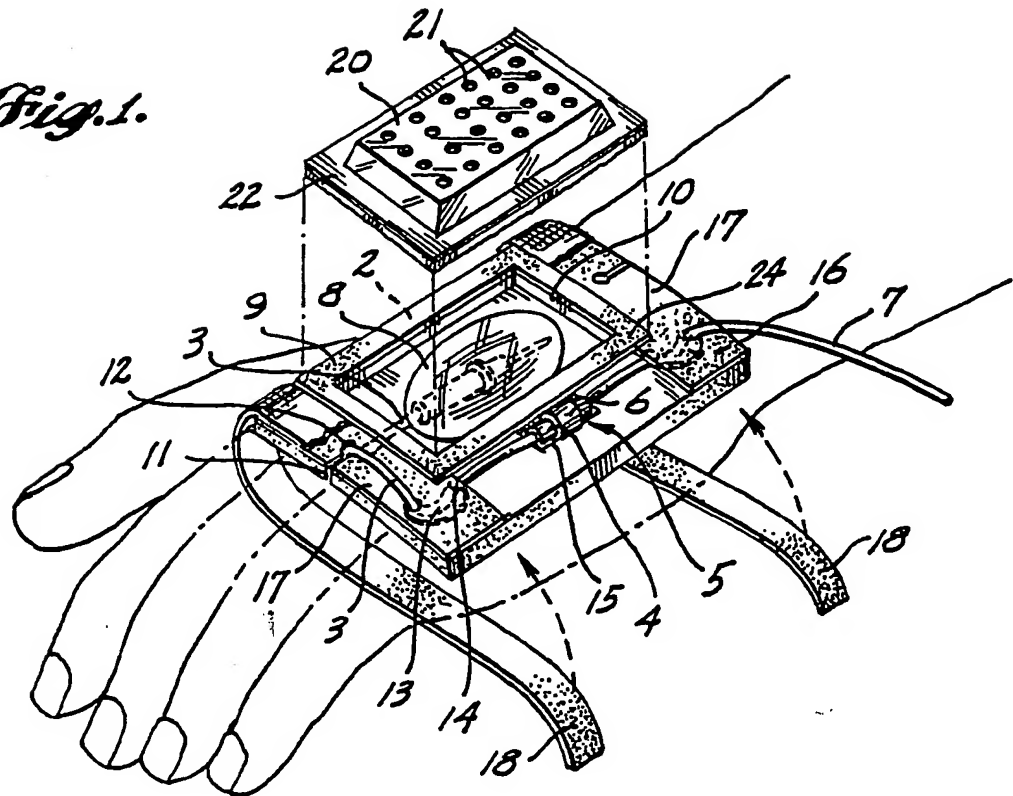


Fig. 2.

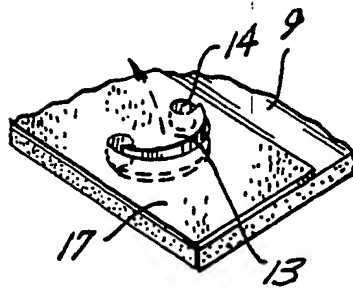


Fig. 3.

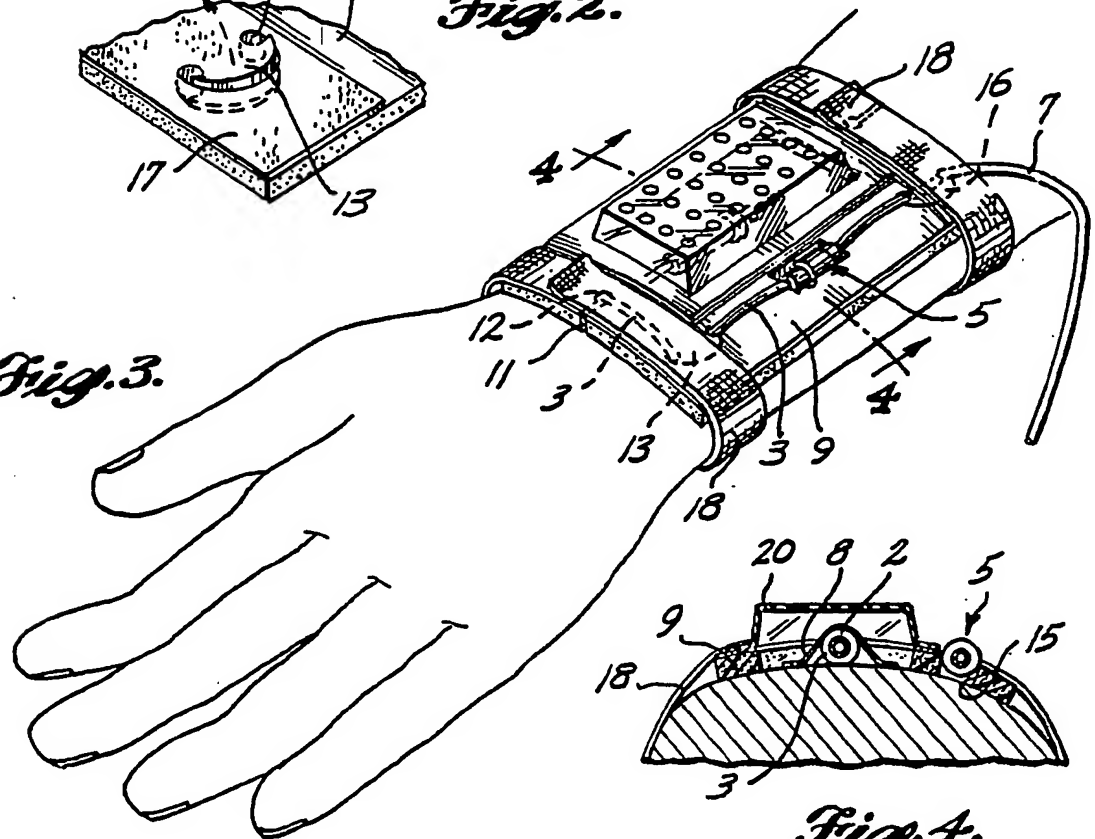
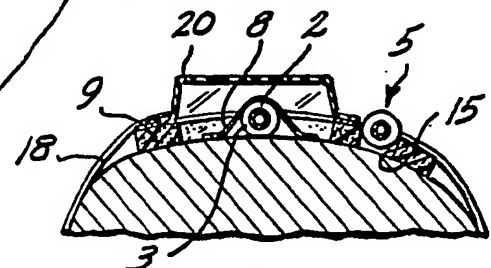


Fig. 4.



2/3

Fig. 5.

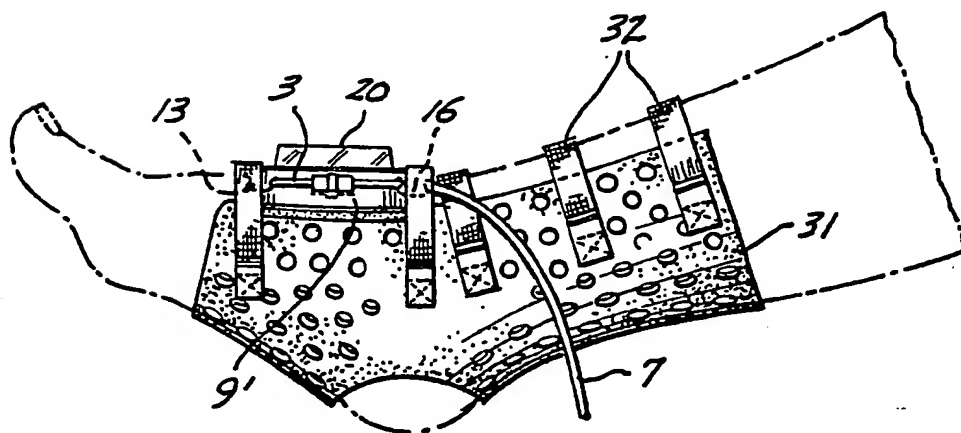
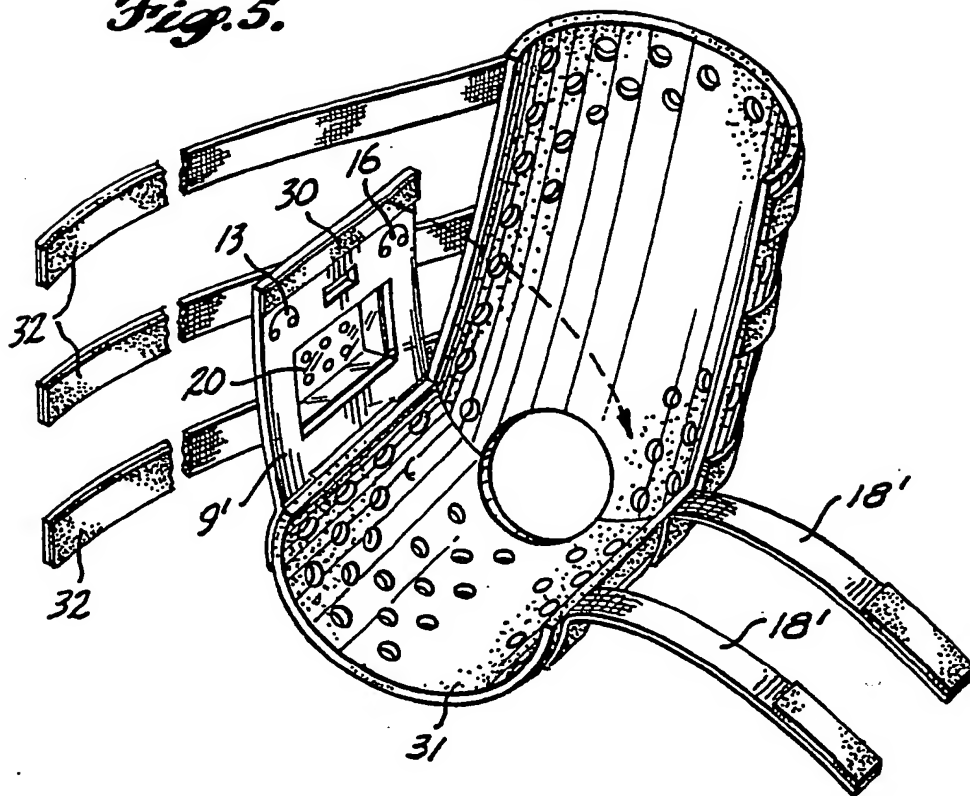


Fig. 6.

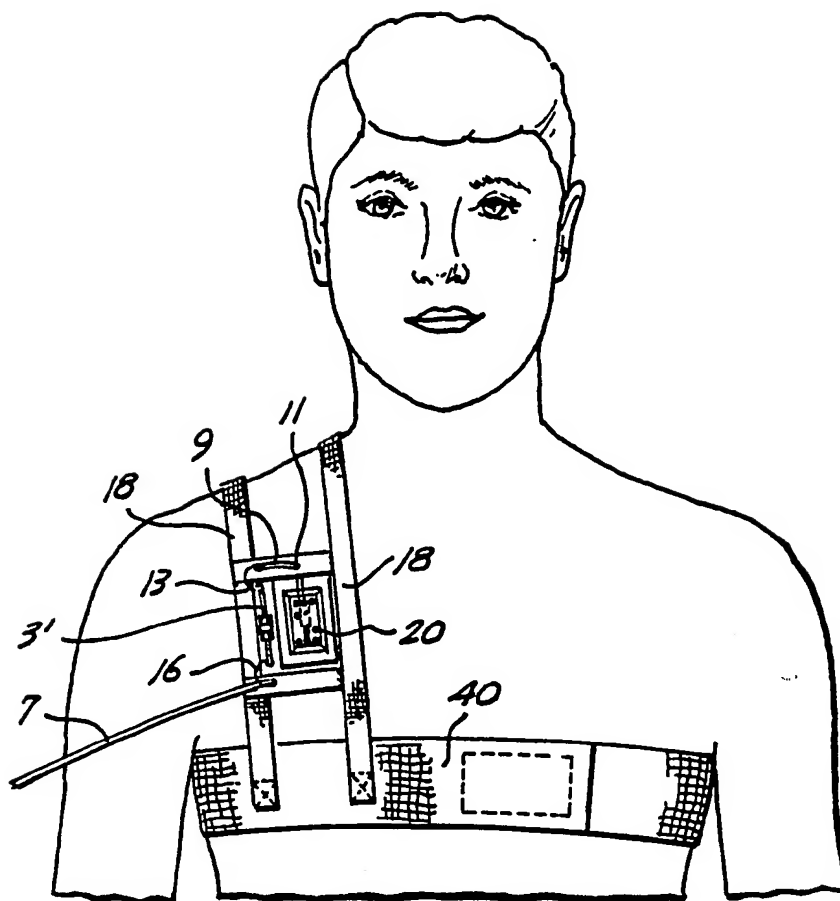


Fig. 7.

INTERNATIONAL SEARCH REPORT

International Application No PCT/US87/00967

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ³		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC(4): A61M 5/32		
U.S. Cl. 604/174, 179 128/133, DIG. 6		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁴		
Classification System	Classification Symbols	
U.S.	604/174, 179, 180; 128/132, 133, DIG. 6, 153	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category ⁶	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
X Y	US, A, 3,900,026, WAGNER, 19 August 1975. (See entire document).	1-3, 11 12
X Y	US, A, 4,517,971, SORBONNE, 21 May 1985. (See the entire document).	1-6 7, 8, 10
Y	US, A, 4,574,798, HEITZMAN, 11 March 1986. (Column 3, lines 33-37).	10
Y	US, A, 4,582,508, PAVELKA, 15 April 1986. (Column 2, lines 22-33).	10
Y	US, A, 4,449,975, PERRY, 22 May 1984. (Column 4, lines 1-7).	12
A	US, A, 4,516,968, MARSHALL ET AL, 14 May 1985. (Column 2, lines 44-51).	
A	US, A, 4,197,245, BROWNING, 15 April 1980. (See Fig. 1).	
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>[*] Special categories of cited documents: ¹⁵</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search ²		Date of Mailing of this International Search Report ³
08 July 1987		23 JUL 1987
International Searching Authority ¹		Signature of Authorized Officer ¹⁰
ISA/US		S. C. Pellegrino

Form PCT/ISA/210 (second sheet) (May 1986)